

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

<b>In re Ethicon, Inc. Pelvic Repair System Products Liability Litigation</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO ETHICON WAVE 4 CASES: <i>Identified in Exhibit A</i></b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE  
EXPERT TESTIMONY OF STEVEN GOLDWASSER, MD**

Plaintiffs in the above-captioned consolidated cases respectfully move this Court to exclude the testimony of Steven Goldwasser, M.D., a proffered expert witness for the Defendants, regarding Ethicon's Prolift mesh product. Dr. Goldwasser does not possess the necessary qualifications to render many of his opinions. Additionally, Dr. Goldwasser's opinions are not based on sufficient facts or data. Most importantly, he has not established that he followed a reliable methodology to reach many of his opinions.

Specifically, Dr. Goldwasser offers opinions regarding the *adequacy* of Ethicon's warnings in IFUs, but he lacks the requisite qualifications and has not reliably reviewed the actual regulations to testify regarding the adequacy of warnings. Despite the Court consistently excluding state-of-mind testimony, Dr. Goldwasser seeks to testify as to the state of mind of all doctors, including what he erroneously believes *all* doctors knew about these products. Accordingly, Plaintiffs respectfully request that the Court exclude Dr. Goldwasser's opinions and testimony as discussed herein.

**LEGAL STANDARD**

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

The function of the Court is to act as a gatekeeper when it comes to expert testimony: “[E]xpert witnesses have the potential to be both powerful and quite misleading[;]” and it is incumbent upon the Court to “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 595 (1993)). Courts should focus on expert witnesses’ “principles and methodology, not on the conclusions that they generate.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because “*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder.” *Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4<sup>th</sup> Cir. 1996). Additionally, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014) and *Sanchez v. Boston Sci. Corp.*, No. 2:1-cv-5762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014).

## **ARGUMENT**

The Court should prohibit Dr. Goldwasser, a urogynecologist designated as a Defense expert, from presenting a number of opinions about the Prolift mesh device because he is unqualified and has not established that he has followed any reliable methodology.

### **Dr. Goldwasser's Opinions Broadly Exceed His Qualifications and Experience**

Dr. Goldwasser is a pelvic floor and reconstructive surgeon. However, he seeks to offer broad overreaching opinions that exceed his qualifications involving FDA regulations, biomechanical engineering, histopathology, and epidemiology. Dr. Goldwasser has not established that he is uniquely qualified in these areas by knowledge, skill, experience, training, or education. He has no direct training in any of these areas. He has no direct personal experience in any of these specialties. Just because Dr. Goldwasser reads literature in his private practice, he is no more qualified to make broad sweeping conclusions about the epidemiological evidence than an attorney who reads medical literature is qualified to provide expert testimony regarding surgical technique. More importantly, he has not established that he followed a reliable methodology in reaching opinions in any of these areas. Dr. Goldwasser's expert testimony must be limited to areas where he is sufficiently qualified and has established followed a reliable methodology. His opinions that do not satisfy these requirements must be excluded.

#### **I. DR. GOLDWASSER'S OPINIONS REGARDING THE ADEQUACY OF ETHICON'S WARNINGS SHOULD BE EXCLUDED BECAUSE HE IS UNQUALIFIED TO RENDER THESE OPINIONS AND HE FOLLOWED AN UNRELIABLE METHODOLOGY.**

Dr. Goldwasser seeks to testify that Ethicon provided *adequate* warnings in its IFUs. *See* Report at 30. However, he is not qualified to offer opinions regarding regulatory compliance and he did not employ a reliable methodology to reach these opinions, in part, because he has not

reliably reviewed the regulatory or internal Ethicon requirements for warnings.<sup>1</sup> *See, e.g., In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2:12-md-02327, Doc. No. 2701 at 9-10 (S.D. W. Va. Aug. 31, 2016) (an expert “must possess additional expertise to offer testimony about what information should or should not be included in an IFU.”) (internal citation omitted). Dr. Goldwasser’s explanations for his conclusion that Ethicon provided adequate warnings is not supported by any reliable basis – he simply is not an expert on these regulations and did not follow any reliable methodology in reviewing the applicable standards. Accordingly, his opinions related to the adequacy of Ethicon’s warnings should be excluded in their entirety.

Dr. Goldwasser cannot articulate a reliable, consistent explanation for how he reached this opinion regarding the adequacy of Ethicon’s warnings. He admitted that this opinion is “based on [his] overall knowledge of the product, but not specifically regulation per se.” Transcript of Deposition of Dr. Steven Goldwasser, 3/29/2017, (“Goldwasser dep.”) (attached as Exhibit C) at 223:5-17. Later, in response to Ethicon’s leading questions, Dr. Goldwasser changed course and testified that he considered the federal regulations in reaching his labeling opinions. Goldwasser dep. 226:17-21. However, he acknowledged that his labeling “conclusions are based on what [he] presented [in his Report].” Goldwasser dep. 224:3-13. In his Report, Dr. Goldwassser only discusses one brief subsection of the CFR governing labeling, with no explanation as to how he disregarded the majority of the other provisions. *See Report at 31; Goldwasser dep. 227:5-25.*

Dr. Goldwasser testified that he does not consider himself an expert in (1) FDA regulations; (2) in regulations or requirements regarding IFU’s; nor (3) medical device industry practices. Goldwasser dep. 121:6-19. Dr. Goldwasser simply has no experience, training, or qualifications

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<sup>1</sup> Wave 4 Expert Report of Steven Goldwasser, M.D, February 15, 2017 (attached as Exhibit B) (“Report”).

to offer opinions regarding the adequacy of warnings. Accordingly, these opinions should be excluded.

**II. DR. GOLDWASSER DID NOT FOLLOWED A RELIABLE METHODOLOGY IN REACHING HIS DEGRADATION OPINIONS AND INSTEAD ADMITTED THAT HIS REPORT IS INACCURATE.**

In his report, Dr. Goldwasser states that he is not aware of any evidence showing that the polypropylene degrades. Report at 28. In deposition, Dr. Goldwasser explicitly admitted that this opinion is dead wrong. When asked if this opinion was not accurate because he knows that evidence exists, he testified, “There is evidence on both sides of the debate, correct.” Goldwasser dep. 222:8-17. He further testified, “There are articles on both sides of the argument, one saying it degrades, another says it doesn’t.” Goldwasser dep. 194:21-24.

Then Dr. Goldwasser testified that even if even if the mesh does degrade, he does not think there is any clinical significance. Report at 28. Dr. Goldwasser was then presented with an article by Dr. Iakovlev which Dr. Goldwasser included on his reliance list. Goldwasser dep. 195:19-196:1. Dr. Goldwasser acknowledged that article concluded, “Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation.” Goldwasser dep. 197:14-20. However, Dr. Goldwasser could not provide any scientific reason or explanation for discounting this evidence, that he apparently reviewed and relied upon, and that contradicted his opinion.

Dr. Goldwasser is not uniquely qualified to offer testimony about the biomechanical degradation of polypropylene. He admits he has never looked at mesh under a microscope or electron scanning microscope, and he admits he does not read the biomaterials literature. Goldwasser dep. 196:2-18. He makes broad, over-reaching statements regarding the complete absence of relevant evidence, which he later necessarily admits is wrong. When confronted with

evidence that directly contradicts his opinions, he cannot offer any reliable explanation. Accordingly, Dr. Goldwasser has not demonstrated he followed a reliable methodology in reaching his degradation opinions, and they should be excluded.

**III. DR. GOLDWASSER UNRELIABLY ASSUMES HE KNOWS WHAT ALL DOCTORS AND PATIENTS KNOW.**

The Court has “consistently prohibited state-of-mind testimony, as allowing such testimony would usurp the jury’s fact-finding duties.” *See, e.g., In re. Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2:12-md-02327, Doc. No. 2727 at 7 (S.D. W. Va. Sept. 2, 2016). However, in his reports, Dr. Goldwasser discloses several opinions regarding what *he thinks* other doctors know.

For example, he unreliably assumes that all pelvic floor surgeons know of the risks associated with the Prolift device. Report at 31. However, in deposition, he explicitly admitted that different doctors read different journals for different specialties and have different knowledge sets. Goldwasser dep. 62:19-63:24. He also admitted he is not aware of any evidence showing what all doctors are aware of. Goldwasser dep. 222:18-223:1.

Because Dr. Goldwasser has no reliable basis for these opinions and consistent with the Court’s earlier rulings, these opinions should be excluded.

**IV. DR. GOLDWASSER HAS NOT ESTABLISHED THAT HIS OPINIONS BASED ON HIS PERSONAL EXPERIENCE ARE RELIABLE.**

Dr. Goldwasser asserts that his opinions regarding the safety and efficacy of the Prolift device are based, in part, on his personal experience – including a database that Dr. Goldwasser maintains that tracks *every* patient in which he has ever implanted transvaginal mesh. Plaintiffs have repeatedly requested that Dr. Goldwasser provide all data, summaries, reports, and analyses available regarding this database. Dr. Goldwasser testified that this data is easily accessible.

Goldwasser dep. 50:1-4. To date, Ethicon has not produced any of this information (other than publicly available abstracts). Plaintiffs cannot assess the reliability of Dr. Goldwasser's methodology or the sufficiency of these underlying facts or data without this information. Accordingly, Plaintiffs reserve their right to supplement this motion regarding Dr. Goldwasser's expert testimony.

### **CONCLUSION**

Dr. Goldwasser does not possess the necessary qualifications to render many of his opinions, which is the first requirement for an expert witness to satisfy under the Rules. Additionally, Dr. Goldwasser has not established that he followed a reliable methodology in reaching his vague and overly broad opinions or that he has sufficient reliable facts or data to support them. For the reasons stated above, Plaintiffs respectfully request this Court exclude Dr. Goldwasser's opinions.

Respectfully submitted this 13<sup>th</sup> April, 2017.

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the list of participants registered to receive service in this MDL.

/s/ Shea N. Shaver